Next 1 Page(s) In Document Exempt

Approved For Release 2003/08/13 : CIA-RDP84B00890R000400010025-8

24 September 1981

MEMORANDUM FOR: Deputy Director for Administration

VIA: Robert A. Ingram, M.D.
Director of Medical Services

STAT FROM: [redacted]
Chief, Psychiatric Division

SUBJECT: Attendance at Workshop on Whistle Blowing in Biomedical Research

1. On 21 and 22 September 1981, I attended a Workshop on Whistle Blowing in Biomedical Research. This workshop was sponsored by the President's Commission for the Study of Ethical Problems in Medicine and Research; the American Association for the Advancement of Science; and Medicine in the Public Interest -- a Boston-based public interest group. I attended as the Agency Liaison Officer to the Commission, which had requested attendance.

2. The Commission's interest in the subject of whistle blowing arises from its mandate to monitor research in Federal agencies, and to make periodic reports to the President and to Congress. Whistle blowing is a complex and varied phenomenon which can have marked consequences for the institution, the accused, and the whistle blower. While the Agency is evidently conducting no human research intramurally at this time and funds only a few contracts for such activity, compartmentation and the need-to-know principle theoretically can compete with the openness and academic freedom of scientific research conducted on humans in more traditional research centers, thus rendering the Agency vulnerable to undetected wrongdoing, as in the past, as well as whistle blowing.

3. Whistle blowing is less likely to occur in a setting of solid supervision and accountability. A commitment by the institution to consider allegations of fraud and unethical conduct seriously is important in setting a tone of seriousness in this matter. The charge in 1973 of the Director of Central Intelligence -- with updates -- to employees to report cases of suspected misconduct appears to set the proper framework within this Agency. Furthermore, the development of a planned course of action when fraud, mistake or undue risk to human subjects is uncovered can be developed as a part of the General Assurances within the Institutional Review Board framework. In the particular case of the Agency, these matters can be considered and developed by the Agency's Human Subject Research Panel (HSRP). In

addition, the authority to discontinue specific research, and whom to contact in the case of questions, can be included. Further, each researcher can be provided with a guideline as to the Agency's expectations with respect to the protection of human subjects in research. Since the Commission's definition of research is a very broad one, employees need to be aware that certain activities may fall within the Commission's mandate. A brief item on this subject is being prepared for the Director of Central Intelligence to be included in his periodic communications with employees. Finally, by education and example, when allegations arise, the Agency should demonstrate that while it will seek to protect those who call attention to wrongdoing, so it will seek to protect those who are accused by conducting a prompt, timely review of the allegations.

4. In the case of external contracts which the Agency funds, the periodic evaluation of progress reports and the conduct of on-site inspections, with the authority to shut down contracts if necessary, follows the FDA-NIH model.

5. The single most innovative idea which I heard during the course of the workshop was the suggestion that proposals for human research be accompanied by the proposal for adequate monitoring of the research. Such a proposal has the advantage of drawing on the knowledgeability of the would-be investigator at a time when research and the means for funding such activity are becoming more complex.

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Next 5 Page(s) In Document Exempt

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POWER OF ATTORNEY

STAT I, [redacted] do hereby appoint [redacted] STAT

as my attorney in fact, giving her the full power and authority to act in my stead in all matters of any kind or nature, wherever situated; and more specifically, to sign all documents, with the understanding that they be legally binding on me, re-negotiate loans, and to deal with any and all creditors as she may deem appr9priate.

SIGNED this 28th day of October, 1978.

[redacted] STAT

Next 21 Page(s) In Document Exempt

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